REMARKS

I. Status of the Claims

Reconsideration of this application is respectfully requested. The Examiner has maintained the restriction requirement and acknowledged Applicant's election with traverse of the group I claims 1-6 and 20-25, drawn to pharmaceutical compositions for regulating bone-forming activity in a mammal. Therefore, claims 7-19 and 26-43 have been withdrawn from consideration. Claim 5 has been cancelled without prejudice. Therefore, claims 1-4, 6, and 20-25 are under examination. Applicant notes that should Group I claims be deemed allowable, the withdrawn method of use claims, which depend from the allowable claims of Group I, will be eligible for rejoinder according to M.P.E.P. 821.04(b).

Claim 1 has been amended to recite "an antibody against a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2." Claims 2, 20, and 22-25 have been similarly amended. Support for this amendment may be found throughout the specification and in particular in paragraphs 12 and 47 of the published application (U.S. Patent Application No. 20040115195).

No new matter has been added.

II. Status of the Specification

The first paragraph of the specification after the title has been amended to correct a typographical error in the priority claim.

III. Claim Objections

Claim 1 is objected to for reciting non-elected species. Claim 1 has been amended without prejudice or disclaimer to delete reference to the non-elected species.

Claim 25 is objected to as being dependent upon a rejected base claim. The Examiner states that claim 25 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 25 has been amended as described above. In view of the present amendments, claim 25 is believed to be in condition for allowance.

IV. Claim Rejections

A. Rejections under 35 U.S.C. §112, first paragraph; Written Description

Claims 1-6 and 20-24 have been rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter that was not described in a way to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

The Examiner states that Applicant has described an antibody specific for sFRP-1 of SEQ ID NO: 2 encoded by the polynucleotide of SEQ ID NO: 1. He reasons that applicant has not described other antibodies against fragments of sFRP or against sFRPs of any other species that have binding specificity to sFRP-1. The Examiner asserts that the specification does not disclose a representative number of species of sFRPs of the scope of the genus of sFRPs recited in claims 1 and 20. The Examiner concludes that in the absence of sufficient recitation of identifying characteristics, the specification does not provide adequate written description of the claimed genus.

In order to expedite prosecution of the present case, and without conceding to the Examiner's position or the validity of the rejection, Applicant has amended claim 1 to recite "an antibody against a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2." Claims 2, 20, and 22-25 have been similarly amended. Support for this amendment may be found throughout the specification and in particular in paragraphs 12 and 47 of the published application (U.S. Patent Application No. 20040115195).

Based on the foregoing amendments and remarks, Applicant submits that the written description rejections have been obviated. Applicant therefore respectfully requests that these rejections be withdrawn.

B. Rejections under 35 U.S.C. §112, first paragraph; Enablement

Claims 1-6 and 20-24 have also been rejected under 35 U.S.C. §112, first paragraph because the specification, while being enabling for a pharmaceutical composition comprising an antibody that specifically binds to a polypeptide, sFRP-1 of SEQ ID NO:2, allegedly does not

reasonably provide enablement for pharmaceutical compositions comprising antibodies against sFRPs or sFRP fragments of any species.

In order to expedite prosecution of the present case, and without conceding the Examiner's position or the validity of the rejection, Applicant has amended claim 1 to recite "an antibody against a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2" as described above. Claims 2, 20 and 22-24 have been similarly amended. Regarding sFRP fragments, the specification at paragraph 106 of the published application describes a number of desirable fragments of SEQ ID NO:2, which could be used to generate antibodies for regulating bone-forming activity. Generating an antibody against a protein or protein fragment is routine for one skilled in the art. Thus, the presently claimed compositions are enabled.

Based on the foregoing amendments and remarks, Applicant submits that the rejections under 35 U.S.C. § 112, first paragraph, have been obviated. Applicant therefore respectfully requests that these rejections be withdrawn.

B. Rejections under 35 U.S.C. §102(e)

Claims 1, 3-6, and 20-24 have been rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,433,155 ("Umansky"). The Examiner asserts that Umansky discloses a pharmaceutical composition comprising an antibody against a polypeptide of the SARP (secreted apoptosis related protein) family that includes murine msarp1, as well as human hsarp1, hsarp2, and hsarp3. (*See*, Office Action, page 8).

According to the Examiner, SARP-2 is also known as sFRP-1 and shares 99.7% similarity to the sFRP protein of SEQ ID NO:2 of the present application and exhibits 100% identity to amino acids 217-231. The Examiner admits that Umansky does not expressly teach pharmaceutical compositions for regulating bone-forming activity in a mammal. The Examiner concludes, however, that this function would be inherent in the composition, since it allegedly has exactly the same components recited in the claims. The Examiner reasons that a compound and all of its properties are inseparable. (*See*, Office Action, page 8).

Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. *See* MPEP § 2131 (8th Ed., Rev. 4, Jan. 2006). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claims 1 and 20 have been amended to recite "sFRP-1 protein of SEQ ID NO:2," as described above. The SARP proteins described by Umansky are not identical to the sFRP-1 protein of SEQ ID NO:2. Additionally, Umansky does not teach a pharmaceutical composition for regulating bone-forming activity in a mammal. Thus, Umansky fails to anticipate claims 1, 3-6, and 20-24. Reconsideration of claims 1, 3-6, and 20-24 and withdrawal of the rejections of these claims under 35 U.S.C.§ 102(b) is requested.

C. Rejections under 35 U.S.C. §103(a)

Claim 3 has been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,433, 155 ("Umansky"), in view of Hoang et al. (J. Biol. Chem. 1996, 271(42): 26,131-26,137, ("Hoang").

The Examiner cites Umansky for its teachings relating to a pharmaceutical composition comprising an antibody against a polypeptide of sFRP. The Examiner concedes that Umansky does not disclose that sFRP is from human osteoblast cells or that the bone-forming activity is the regulation of bone growth or bone density.

The Examiner relies on Hoang for teaching tissue distribution of Frzb-1 (sFRP-3) in human embryos. The Examiner asserts that Hoang found that Frzb-1 is expressed in bone cells, and that Frzb-1 plays a role in skeletal morphogenesis (citing Figure 5-7, p. 26,137).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine the teachings of Umansky with those of Hoang to isolate an sFRP protein from human osteoblast cells and to use the composition comprising such an antibody for regulating bone-forming activity in a mammal. (*See*, Office Action, page 9). In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the

differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

For a claim to be obvious under 35 U.S.C. § 103(a), all three of the following criteria must be satisfied:

1. there must be some suggestion or motivation to combine or modify the cited references;
2. there must be a reasonable expectation of success of combining or modifying the cited references; and
3. the combined references must teach each and every limitation of the claimed invention.

Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000). Applicant respectfully submits that these criteria have not been met, and thus traverse this rejection and request reconsideration of claim 3.

Applicant submits that nothing in the cited references teaches or suggests the presently claimed pharmaceutical compositions for regulating bone-forming activity. Specifically, nothing in Umansky or Hoang suggests an sFRP-1 antibody against SEQ ID NO:2 to regulate bone-forming activity. Furthermore, nothing in Hoang provides a reasonable expectation of success of using a pharmaceutical composition containing an sFRP-1 antibody for regulating bone-forming activity.

Furthermore, the Examiner's attempt to cure the deficiency of Umansky with Hoang fails because there is no suggestion in the prior art to combine these references. Both the motivation to combine the relevant elements and the suggestion of success must be found in the prior art to satisfy the requirements for maintaining an obviousness rejection. *In re The Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) ("[b]oth the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure"). While not all of the elements of the presently claimed pharmaceutical composition can be found in the cited references, finding various elements piecemeal in separate references is ***not*** sufficient motivation to combine them to arrive at a claimed invention. *In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998) ("[T]he examiner must show reasons that the skilled artisan, *confronted with the same problems as the inventor and with no*

knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.") (citations omitted, emphasis added).

In conclusion, there is no suggestion in Umansky or Hoang to combine or even modify their products to arrive at presently claimed pharmaceutical compositions for regulating bone-forming activity. Therefore, reconsideration of claim 3 and withdrawal of the rejection of this claim under 35 U.S.C.§ 103(a) is requested.

CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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